

## REMARKS

The Examiner is thanked for entering the submission filed August 4, 2008 and withdrawing the rejection of Claim 22 under 35 U.S.C. §112, first paragraph.

Claims 1-6, 16-17 and 21 were rejected under 35 U.S.C. §103(a) as being unpatentable over Oshlack et al. (Oshlack) in view of Meissner. The Examiner noted that the rejection over Oshlack was maintained but it was not repeated in the Office Action of September 30, 2008. For this reason, clarification is requested. Claims 18 and 22 were not rejected and it is assumed that these claims are free of the prior art.

Reconsideration of this rejection is requested.

Claim 1 recites that the composition contains specific hydrocolloids and excipients including the recited components. This specific formulation is not made obvious by Oshlack who mentions many formulations but none having the components of claim 1. It is not seen how a reference can make obvious a formulation having ingredients that are not disclosed by the reference. Since Oshlack does not mention the ingredients of claim 1, the composition of claim 1 cannot be made based on the teachings of Oshlack.

Claims 6 and 22 recite a formulation or method where the pellets are enteric coated pellets. This formulation is not made obvious by Oshlack and or Meissner who do not disclose an enteric coated formulation. Claim 16 points out a specific three pellet formulation where the pellets are formulated to release the drugs in specific anatomical locations of the small intestine. This formulation is also not made obvious by Oshlack. Amended claim 22 points out a

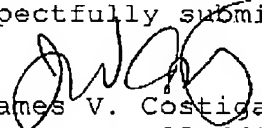
method of treating constipation caused by opiates where the opiate antagonist is administered in the form of enteric coated pellets. Nothing in Oshlack or Meissner makes claim 22 obvious.

The Meissner reference recites that each patient must be titrated with the amount of naloxone antagonist to determine the dose for treating or preventing constipation. This makes each patient a research project and does not provide information as to how to make a dosage form. The claims of the present application point out that microcrystalline cellulose, propylene glycol alginate, zein and magnesium stearate are used to form a viscous, non-injectable matrix, when the dosage form is contacted with water. This formulation releases the naloxone at the termination end of the small intestine and in the large intestine and thus prevents constipation without the need to adjust or titrate the dose to experimentally determine what dose will prevent constipation.

The cited references do not make obvious the claimed composition and for these reasons, the rejection should be withdrawn.

An early and favorable action is earnestly solicited.

Respectfully submitted,

  
James V. Costigan  
Reg. No. 25,669

Hedman & Costigan, P.C.  
1185 Avenue of the Americas  
New York, NY 10036  
(212) 302-8989